K120031

MAR 16 2012

510(k) Summary
Chesapeake Spinal System
K2M, Inc.

This safety and effectiveness summary for the Aleutian IBF System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
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Date Prepared: July 16, 2009

Contact Person :
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Telephone: 703-777-3155

2. Tradename: Chesapeake Spinal System
Common Name: Intervertebral Body Fusion Device
Classification Name: OVD
Regulation Number: 888.3080

3. Description of the device:

The Chesapeake Spinal System consists of PEEK spacers and titanium bone screws for intervertebral body fusion, without the need for supplementary fixation. The spacers are hollow tube structures that can be packed with bone graft and allow for passage of screws for fixation to the vertebral body. The bone contacting surfaces of the implants have machined teeth which are designed to engage with the vertebral body endplates. Tantalum markers are embedded within the spacers identify the location and orientation of the implants to radiographically. Implants with footprints ranging from 24x30mm-28x36mm are available to accommodate anatomical variations. The purpose of this submission is to add 30x40mm footprints to the system.

Materials:

PEEK-OPTIMA LT1	F2026
TANTALUM	F560
TITANIUM ALLOY	F1472
CP TITANIUM	F67

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the lumbar segments of the spine.

4. Intended Use:

When used as a cervical intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Lumbar I implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The Chesapeake spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the Chesapeake spacers are intended to be used with the bone screws provided. When using a 2 screw implant, 2 screws must be used. When using a 3 screw implant 3 screws must be used.

5. Predicate or legally marketed devices which are substantially equivalent:

Documentation was provided which demonstrated that the subject Chesapeake Spinal System components are substantially equivalent to the K2M Aleutian Interbody Spacer Systems (K051454, K082698), Surgicraft Stalif System (K073109), Synthes Synfix (K062083, K072253), Spinal Elements (K083475), and Biomet Solitaire (K081501).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

There are no significant differences between the Chesapeake Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

K2M, Inc.
% Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

Re: K120031
Trade/Device Name: Chesapeake Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: February 16, 2012
Received: February 17, 2012

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120031

510(k) Number (if known):

Device Name : **Chesapeake Spinal System**

Indications For Use :

When used as a cervical intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Lumbar I implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The Chesapeake spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the Chesapeake spacers are intended to be used with the bone screws provided. When using a 2 screw implant, 2 screws must be used. When using a 3 screw implant 3 screws must be used.

Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RPJ

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120031